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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,528	09/26/2001	Y. Tom Tang	PF-0701 USA	3765

7590 05/20/2002

LEGAL DEPARTMENT
INCYTE GENOMICS, INC.
3160 PORTER DRIVE
PALO ALTO, CA 94304

EXAMINER

HADDAD, MAHER M

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 05/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/965,528	TANG ET AL.	
	Examiner	Art Unit	
	Mahe M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-107 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-107 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: ____ |

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DETAILED ACTION

Sequence Compliance

1. The instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

The following ERROR(S) IN CRF HAS BEEN CORRECTED BY STIC: Inserted left alignment margin between sequence of 150 and 151 field identifiers

Restriction Requirement

2. Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claims 1, 2, 17-18 and 56, drawn to an isolated polypeptide comprising SEQ ID NO: 1; classified in Class 530, subclasses 395.
- II. Claims 1, 2, 17-18 and 57, drawn to an isolated polypeptide comprising SEQ ID NO: 2; classified in Class 530, subclasses 395.
- III. Claims 1, 2, 17-18 and 58, drawn to an isolated polypeptide comprising SEQ ID NO: 3; classified in Class 530, subclasses 395.
- IV. Claims 1, 2, 17-18 and 59, drawn to an isolated polypeptide comprising SEQ ID NO: 4; classified in Class 530, subclasses 395.
- V. Claims 1, 2, 17-18 and 60, drawn to an isolated polypeptide comprising SEQ ID NO: 5; classified in Class 530, subclasses 395.

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- VI. Claims 1, 2, 17-18 and 61, drawn to an isolated polypeptide comprising SEQ ID NO: 6; classified in Class 530, subclasses 395.
- VII. Claims 1, 2, 17-18 and 62, drawn to an isolated polypeptide comprising SEQ ID NO: 7; classified in Class 530, subclasses 395.
- VIII. Claims 1, 2, 17-18 and 63, drawn to an isolated polypeptide comprising SEQ ID NO: 8; classified in Class 530, subclasses 395.
- IX. Claims 1, 2, 17-18 and 64, drawn to an isolated polypeptide comprising SEQ ID NO: 9; classified in Class 530, subclasses 395.
- X. Claims 1, 2, 17-18 and 65, drawn to an isolated polypeptide comprising SEQ ID NO: 10; classified in Class 530, subclasses 395.
- XI. Claims 1, 2, 17-18 and 66, drawn to an isolated polypeptide comprising SEQ ID NO: 11; classified in Class 530, subclasses 395.
- XII. Claims 1, 2, 17-18 and 67, drawn to an isolated polypeptide comprising SEQ ID NO: 12; classified in Class 530, subclasses 395.
- XIII. Claims 1, 2, 17-18 and 68, drawn to an isolated polypeptide comprising SEQ ID NO: 13; classified in Class 530, subclasses 395.
- XIV. Claims 1, 2, 17-18 and 69, drawn to an isolated polypeptide comprising SEQ ID NO: 14; classified in Class 530, subclasses 395.
- XV. Claims 1, 2, 17-18 and 70, drawn to an isolated polypeptide comprising SEQ ID NO: 15; classified in Class 530, subclasses 395.
- XVI. Claims 1, 2, 17-18, and 71, drawn to an isolated polypeptide comprising SEQ ID NO: 16; classified in Class 530, subclasses 395.
- XVII. Claims 1, 2, 17-18 and 72, drawn to an isolated polypeptide comprising SEQ ID NO: 17; classified in Class 530, subclasses 395.
- XVIII. Claims 1, 2, 17-18 and 73, drawn to an isolated polypeptide comprising SEQ ID NO: 18; classified in Class 530, subclasses 395.
- XIX. Claims 1, 2, 17-18 and 74, drawn to an isolated polypeptide comprising SEQ ID NO: 19; classified in Class 530, subclasses 395.
- XX. Claims 1, 2, 17-18 and 75, drawn to an isolated polypeptide comprising SEQ ID NO: 20; classified in Class 530, subclasses 395.

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- XXI. Claims 1, 2, 17-18 and 76, drawn to an isolated polypeptide comprising SEQ ID NO: 21; classified in Class 530, subclasses 395.
- XXII. Claims 1, 2, 17-18 and 77, drawn to an isolated polypeptide comprising SEQ ID NO: 22; classified in Class 530, subclasses 395.
- XXIII. Claims 1, 2, 17-18 and 78, drawn to an isolated polypeptide comprising SEQ ID NO: 23; classified in Class 530, subclasses 395.
- XXIV. Claims 1, 2, 17-18 and 79, drawn to an isolated polypeptide comprising SEQ ID NO: 24; classified in Class 530, subclasses 395.
- XXV. Claims 1, 2, 17-18 and 80, drawn to an isolated polypeptide comprising SEQ ID NO: 25; classified in Class 530, subclasses 395.
- XXVI. Claims 1, 2, 9-10, 17-18 and 81, drawn to an isolated polypeptide comprising SEQ ID NO: 26; classified in Class 530, subclasses 395.
- XXVII. Claims 4-5, 9-10, 12 and 82, drawn to an isolated polynucleotide of SEQ ID NO: 27, classified in Class 536, subclass 23.5.
- XXVIII. Claims 4-5, 9-10, 12 and 83, drawn to an isolated polynucleotide of SEQ ID NO: 28, classified in Class 536, subclass 23.5.
- XXIX. Claims 4-5, 9-10, 12 and 84, drawn to an isolated polynucleotide of SEQ ID NO: 29, classified in Class 536, subclass 23.5.
- XXX. Claims 4-5, 9-10, 12 and 85, drawn to an isolated polynucleotide of SEQ ID NO: 30, classified in Class 536, subclass 23.5.
- XXXI. Claims 4-5, 9-10, 12 and 86, drawn to an isolated polynucleotide of SEQ ID NO: 31, classified in Class 536, subclass 23.5.
- XXXII. Claims 4-5, 9-10, 12 and 87, drawn to an isolated polynucleotide of SEQ ID NO: 32, classified in Class 536, subclass 23.5.
- XXXIII. Claims 4-5, 9-10, 12 and 88, drawn to an isolated polynucleotide of SEQ ID NO: 33, classified in Class 536, subclass 23.5.
- XXXIV. Claims 4-5, 9-10, 12 and 89, drawn to an isolated polynucleotide of SEQ ID NO: 34, classified in Class 536, subclass 23.5.

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- XXXV. Claims 4-5, 9-10, 12 and 90, drawn to an isolated polynucleotide of SEQ ID NO: 35, classified in Class 536, subclass 23.5.
- XXXVI. Claims 4-5, 9-10, 12 and 91, drawn to an isolated polynucleotide of SEQ ID NO: 36, classified in Class 536, subclass 23.5.
- XXXVII. Claims 4-5, 9-10, 12 and 92, drawn to an isolated polynucleotide of SEQ ID NO: 37, classified in Class 536, subclass 23.5.
- XXXVIII. Claims 4-5, 9-10, 12 and 93, drawn to an isolated polynucleotide of SEQ ID NO: 38, classified in Class 536, subclass 23.5.
- XXXIX. Claims 4-5, 9-10, 12 and 94, drawn to an isolated polynucleotide of SEQ ID NO: 39, classified in Class 536, subclass 23.5.
- XL. Claims 4-5, 9-10, 12 and 95, drawn to an isolated polynucleotide of SEQ ID NO: 40, classified in Class 536, subclass 23.5.
- XLI. Claims 4-5, 9-10, 12 and 96, drawn to an isolated polynucleotide of SEQ ID NO: 41, classified in Class 536, subclass 23.5.
- XLII. Claims 3-7, 9-10, 12-13 and 97, drawn to an isolated polynucleotide of SEQ ID NO: 42, classified in Class 536, subclass 23.5.
- XLIII. Claims 4-5, 9-10, 12 and 98, drawn to an isolated polynucleotide of SEQ ID NO: 43, classified in Class 536, subclass 23.5.
- XLIV. Claims 4-5, 9-10, 12 and 99, drawn to an isolated polynucleotide of SEQ ID NO: 44, classified in Class 536, subclass 23.5.
- XLV. Claims 4-5, 9-10, 12 and 100, drawn to an isolated polynucleotide of SEQ ID NO: 45, classified in Class 536, subclass 23.5.
- XLVI. Claims 4-5, 9-10, 12 and 101, drawn to an isolated polynucleotide of SEQ ID NO: 46, classified in Class 536, subclass 23.5.
- XLVII. Claims 4-5, 9-10, 12 and 102, drawn to an isolated polynucleotide of SEQ ID NO: 47, classified in Class 536, subclass 23.5.
- XLVIII. Claims 4-5, 9-10, 12 and 103, drawn to an isolated polynucleotide of SEQ ID NO: 48, classified in Class 536, subclass 23.5.
- XLIX. Claims 4-5, 9-10, 12 and 104, drawn to an isolated polynucleotide of SEQ ID NO: 49, classified in Class 536, subclass 23.5.

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- L. Claims 4-5, 9-10, 12 and 105, drawn to an isolated polynucleotide of SEQ ID NO: 50, classified in Class 536, subclass 23.5.
- LI. Claims 4-5, 9-10, 12 and 106, drawn to an isolated polynucleotide of SEQ ID NO: 51, classified in Class 536, subclass 23.5.
- LII. Claims 4-5, 9-10, 12 and 107, drawn to an isolated polynucleotide of SEQ ID NO: 52, classified in Class 536, subclass 23.5.
- LIII. Claim 8, drawn to a transgenic organism comprising a recombinant of polynucleotide of SEQ ID NO: 16; classified in Class 800, subclasses 8.
- LIV. Claims 11, 31-32, 34, and 36-43, drawn to an antibody which specifically binds to a polypeptide of SEQ ID NO: 16, labeled antibody, and a method of making and preparing; classified in Class 530, subclass 387.3, and 391.1.
- LV. Claims 14-15, drawn to a method of detecting a target polynucleotide in a sample, said target polynucleotide having a sequence of a polynucleotide of SEQ ID NO: 42, the method comprising hybridizing the sample with a probe and detecting the presence or absence of the said hybridization complex, classified in Class 435, subclass 6.
- LVI. Claims 16, drawn to a method of detecting a target polynucleotide in a sample, said target polynucleotide having a sequence of a polynucleotide of SEQ ID NO: 42, the method comprising amplifying target polynucleotide and detecting the presence or absence of the said amplified target, classified in Class 435, subclass 6.
- LVII. Claim 19, drawn to a method for treating a disease or condition associated with decreased expression of functional EXCS, comprising administering to a patient a composition of SEQ ID NO:16, classified in Class 514, subclass 12.
- LVIII. Claim 20 and 27, drawn to a method of screening a compound for effectiveness as an **agonist** of a polypeptide of SEQ ID NO:16, classified in Class 435, subclass 6 and 7.1.
- LIX. Claim 21, drawn to a composition comprising an agonist compound, classified in Class 514, subclass 2.
- LX. Claim 22, drawn to a method for treating a disease or condition associated with decreased expression of functional EXCS, comprising administering to a patient an agonist compound, classified in Class 514, subclass 2.
- LXI. Claim 26, drawn to a method of screening a compound that specifically binds to the polypeptide; classified in Class 435, subclass 6 and 7.1.

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- LXII. Claims 23 and 27, drawn to a method of screening a compound for effectiveness as an **antagonist** of a polypeptide of SEQ ID NO:16; classified in Class 435, subclass 6 and 7.1.
- LXIII. Claim 24, drawn to a composition comprising an antagonist compound and a pharmaceutically acceptable excipient, classified in Class 530, subclass 130.1 and Class 514, subclass 44.
- LXIV. Claim 25, drawn to a method of treating a disease or condition associated with overexpression of functional EXCS, comprising administering to a patient an antagonist, classified in Class 424, subclass 130.1 and Class 514, subclass 44.
- LXV-XCI. Claim 28, drawn to a method of screening a compound for effectiveness in altering expression of a target polynucleotide, wherein said target polynucleotide comprises a sequence of SEQ ID NOS: 27-52 respectively; classified in Class 435, subclass 6.
- XCII-CXVIII. Claim 29, drawn to a method of assessing toxicity of a test compound, comprising treating a biological sample with a probe of SEQ ID NOS: 27-52 respectively, classified in Class 435, subclass 6.
- CXIX. Claim 30, drawn to a diagnostic test for a condition or disease associated with the expression of EXCS in a biological sample comprising combining the biological sample with an antibody against SEQ ID NO:16, classified in Class 435, subclass 7.1.
- CXX. Claims 33 and 35, drawn to a method of diagnosing a condition or disease associated with the expression of EXCS in a subject, comprising administering an antibody against SEQ ID NO: 16, classified in Class 424, subclass 130.1.
- CXXI. Claim 44, drawn to a method of detecting a polypeptide having the amino acid sequence of SEQ IDN ON:16 in a sample, comprising incubating the antibody with a sample. classified in Class 435, subclass 7.1.
- CXXII. Claim 45, drawn to a method of purifying a polypeptide having SEQ ID NO: 16, classified in Class 530, subclass 413.
- CXXIII- CLVIII. Claims 46 and 48-55, drawn to microarray wherein at least one element of the microarray is a polynucleotide of SEQ ID NOS: 26-52 respectively, classified in Class 536, subclass 44.
- CLIX-CLXXXIV. Claim 47, drawn to a method of generating a transcript image of a sample which contains polynucleotides comprising contacting the elements of microarray

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wherein at least one element of the microarray is a polynucleotide of SEQ ID NOS:27-52 respectively, classified in Class 435, subclass 6.

4. Groups I-LIV, LIX, LXIII and CXXIII- CLVIII are different products. Polypeptides, nucleic acids, transgenic organisms, antibodies, agonist and antagonist compounds and microarrays differ with respect to their structures and physicochemical properties; therefore each product is patentably distinct.

5. Groups LV-LVIII, LX-LXII, LXIV- CXXII, and CLIX-CLXXXIV. are different methods. A method of detecting a method of treating, a method of screening, a method of assessing, a method of diagnosing and a method of purifying differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

6. Groups XLII/LV, XLII/LVI, XVI/LVII, XVI/LVIII, LIX/LX, XVI/LXI-LXII, LXIII/LXIV, XXVII-LII/LXV-XCI, XLII/XCII-CXVIII, LIV/CXIX, LIV/ CXX, LIV/ CXXI and CXXIII-CLVIII/ CLIX-CLXXXIV are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group LIV can be used for affinity purification, in addition to the diagnostic tests and methods of detecting recited.

7. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper.

8. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the

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election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

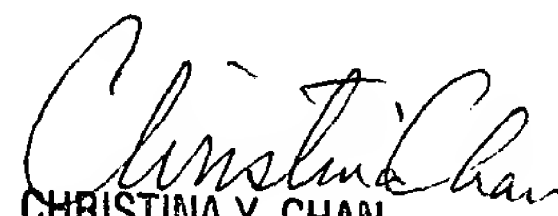
9. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (703) 306-3472. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Maher Haddad, Ph.D.
Patent Examiner
Technology Center 1600
May 18, 2002


CHRISTINA Y. CHAN
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